

U.S. Food and Drug Administration



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Recall -- Firm Press Release

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Novartis Consumer Health Conducts Nationwide Voluntary Recall of Triaminic Vapor Patch Product in U.S.

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FOR IMMEDIATE RELEASE -- Parsippany, NJ, June 19, 2006 -- Novartis Consumer Health announced today it is conducting a nationwide voluntary recall of all Vapor Patch product marketed under the Triaminic brand due to the serious adverse health effects that could result if the product is ingested by the child removing the patch and chewing on it.

Consumers who have Triaminic Vapor Patches should stop using them immediately. There have been multiple reported complaints received, including seizures. Novartis Consumer Health's number one priority is the safety of the consumers who use our products and, therefore, is taking this precautionary action.

All lots are being recalled in both product lines of mentholated cherry scent and menthol scent. Triaminic Vapor Patch contains camphor, eucalyptus oil and menthol.

The reported adverse events associated with swallowing products containing camphor or eucalyptus oils can vary from minor symptoms, such as burning sensation in the mouth, headache, nausea and vomiting, to more severe reactions, such as seizures.

The recall is being conducted with the knowledge of the FDA.

Triaminic Vapor Patch is labeled as a cough suppressant for children two (2) years of age and older. The directions on the label indicate the patch is to be applied to the throat or chest to allow the vapors to reach the nose and mouth. Multiple patches can be applied. Once applied, the patch would be within close reach for a child to remove and place in his/her mouth. The Vapor Patch is a topical cough product applied externally and not for oral consumption.

The product is sold nationwide over the counter at pharmacies and retail stores.

This recall affects only the Vapor Patch. Consumers should immediately discontinue use of this product and return it to their point of purchase for a full refund or discard it. Consumers requiring more information about this recall can contact Novartis Consumer and Professional Affairs Call Center at 1-800-452-0051 or visit www.triaminic.com.

Any adverse reactions experienced with the use of this product should also be reported to the FDA's MedWatch Adverse Event Reporting program online [at www.fda.gov/MedWatch/report.htm], by phone [1-800-FDA-1088], or by returning the postage-paid FDA form 3500 [which may be downloaded from www.fda.gov/MedWatch/getforms.htm] by mail [to MedWatch, 5600 Fishers Lane, Rockvillle, MD 20852-9787] or fax [1-800-FDA-0178].

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